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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,903	05/06/1999	PETER JAMES WATTS	WC131	1775

570 7590 04/01/2004

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/269,903	WATTS, PETER JAMES	
	Examiner	Art Unit	
	Frank I Choi	1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: _____.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Frank Choi

S. MARK CLARDY
PATENT EXAMINER
GROUP 1200
1616

Continuation of 2. NOTE: The claims now contain a coating of a polymer that dissovles at ph 4.5 or above which was not set forth in the claims previously, and, as such, would require further consideration and/or search. Further, claims 42, 43 retain the "means" limitation but claim 58 on which they are dependent does not recites a means. Also, Claim 48 retains the "means" limitation and is dependent on cancelled claim 29..

Continuation of 3. Applicant's reply has overcome the following rejection(s): Rejection of claims 29-41, 44-47,49-57 over 35 USC 112, 2nd paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: The proposed amendment would overcome the part of the 35 USC 112 1st paragraph rejection relative to the "means" limitation provided that claims 42,43,48 are also amended to deleted reference to the "means". Examiner has duly considered Applicant's other arguments but deem them unpersuasive for the reasons set forth in the prior Office Action and the further reasons below. Applicant argues that a chemical compound may be defined by its intended use or function when sufficient criteria are provided such that essential structural aspects of the compound are discernable to a person of skill in the art. Applicant indicates that the compound must be a drug, however, there is no showing that a drug must be useful therapeutically and/or diagnostically. Applicant also indicates that it must have a free acid group, a pKa range of 2.0 to 9.0 and a higher solubility at pH 4.5-8.0 then the free acid form of the drug and that the above are easily determined by routine empircal testing. However, Applicant provides not evidence that the same could be easily determined by routine empirical testing and does not take into account that every other compound not disclosed and even those which are disclosed would have to be tested in order to determine whether they meet said criteria. Further, claim 63 also requires that the drug be tested to determine whether it is effective in the treatment of ulcerative colitis, Crohn's disease, irritable bowel syndrome or inflammatory bowel diseases. Also, the proposed amendment in which the polymer dissolves pH is 4.5 or above greater is not fully enabled as polymers which do not dissolve at pHs of 8 to 4.5, i.e. only dissolve at pH greater than 8, will result in a composition in which no drug will be delivered in the terminal ilium or colon as the pH of the same is described as being in the range of 4.5-8. As such, claims 30-48, 51-54,58-63 are rejected under 35 USC 112 1st paragraph. With respect to the 35 USC 112, 2nd paragraph rejection, claims 42, 43, 48 still recite 'means" without setting forth a polymer which dissolves at the claimed pH, as such, the rejection is maintained with respect to those claims. With respect to the 35 USC 102/103 rejection, Examiner reminds Applicant that in an inherency-based rejection the Graham v. John Deere factors are not applicable, as such, Applicant arguments related to obviousness do not appear to overcome the rejection herein. Applicant argues that if the coating layers described in La Roche were applied to a capsule or tablet the capsule or table would not be able to dissolve or disintegrate in the intestine and the drug-containing pellets inside would never be released. However, Applicant's claims are not all directed to tablets or capsules and the claims which do recite a tablet or capsule do not require that the pellets inside are released. Applicant argues that compositions of the present invention are different because they contain a salt of a drug that are coated with a rate determining membrane and are contained within a table or capsule that is coated with a material that prevents release of the drug until the composition reaches the terminal ileum or colon, and/or individually ocated pellets that are coated with the same coating. However, there is no showing how said description makes the claimed invention different from the explicite disclosure of La Roche. La Roche expressly discloses a salt of a drug in a granule or tablet or capsule which is coated with a layer of acid-soluble coating material that is resistant to both alkali and intestinal juices, a water-soluble intermediate layer and a layer of alkali-soluble coating material that is resistant to acid and gastric juice. Applicant has not shown that the first or second layers are not rate controlling. As such, the prior art meets the limitation of the claimed invention, i.e claims 30-36,38-41,48,51-54, 58-63.